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December 1, 1999

Food and Drug Administration
Document Management Branch
(HFA-305)
5630 Fisher's Lane
Room 1061
Rockville, MD 20852

RE: Docket #97N-484S

Dear Sirs:

I am writing to comment on the proposed FDA regulation allowing the FDA to regulate allograft bone as a medical device.

I am strongly opposed to this regulatory initiative. The safety of allograft bone is adequately ensured by the standards of American tissue banks. There is no requirement for the FDA to further regulate this product. I fear that FDA regulation of this product would increase the cost of allograft bone, and decrease its availability, which would significantly compromise the surgical treatment of patients requiring allograft bone. Further, I am unable to discern any possible benefit to such a regyfation.

I urge the FDA to retract this regulatory proposal in its entirety. It will create problems in the care of patients, and will not enhance patient safety in any way.

Yours sincerely,

Jonathan E. Fuller, MD
NEBRASKA SPINE CENTER LLP

JEF/mjh

97N-484S

C82

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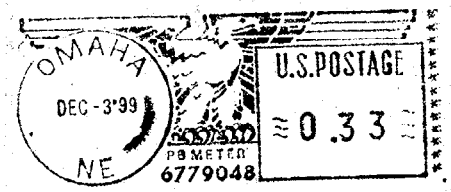
RETURN SERVICE REQUESTED



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